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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,763

08/07/2007

Judith Donovan

38-21(52949)B

6571

7590 03/03/2010
Timothy K. Ball, Ph.D.
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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

03/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,763	Applicant(s) DONOVAN ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 17, 18 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 8, 17-18 and 21-28 are pending. Claims 17-18 are withdrawn from consideration as being drawn to a nonelected invention.
2. The rejections of claim 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement and under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's cancellation of the claim.
3. The rejection of claims 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Carozzi et al (US Patent 7,355,099, filed February 2003) is withdrawn in light of Applicant's cancellation or amendment of the claims.

Claim Objections

4. Claims 21-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. How or where a protein is produced or what method it is used in does not limit a claim to a protein. If applicant wishes to claim a method of using the protein, then a claim should be drawn to, for example, "A method for controlling a lepidopteran insect pest, wherein said method comprises contacting said pest with a pesticidal amount of the protein of claim 8." Claims to a nucleic acid encoding the protein or cell comprising it belong in nonelected Group I.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carozzi et al (US Patent 7,355,099, filed February 2003). The rejection is repeated for the reasons of record as set forth in the Office action mailed 24 July 2009, as applied to claims 8-9 and 12-13. Applicant's arguments filed 18 December 2009 have been fully considered but they are not persuasive.

The claims are drawn to a protein of SEQ ID NO:4.

Carozzi et al teach a protein with 99% identity to the instant SEQ ID NO:4 (their SEQ ID NO:5).

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US-10-782-020A-5
; Sequence 5, Application US/10782020A
; Patent No. 7355099
; GENERAL INFORMATION:
; APPLICANT: Carozzi, Nadine
; APPLICANT: Hargiss, Tracy
; APPLICANT: Koziel, Michael G.
; APPLICANT: Duck, Nicholas B.
; APPLICANT: Carr, Brian
; TITLE OF INVENTION: AXMI-004, A Delta-Endotoxin Gene and
; TITLE OF INVENTION: Methods for Its Use
; FILE REFERENCE: 045600/274139
; CURRENT APPLICATION NUMBER: US/10/782,020A
; CURRENT FILING DATE: 2004-02-19
; PRIOR APPLICATION NUMBER: 60/448,810
; PRIOR FILING DATE: 2003-02-20
; NUMBER OF SEQ ID NOS: 11
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 5
; LENGTH: 601
; TYPE: PRT
; ORGANISM: Bacillus thuringiensis
US-10-782-020A-5
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Query Match 99.0%; Score 3160; DB 3; Length 601;
 Best Local Similarity 99.0%; Pred. No. 5.8e-283;
 Matches 595; Conservative 2; Mismatches 4; Indels 0; Gaps 0;

Qy	1	MNSKEHDYLVKCNLDSDANINMERFDKNDAL EIGMSIVSELIGMIPGGTALQFVFNQLWS	60
Db	1	MNSKEHDYLVKCNLDSDANINMERFDKNDAL EIGMSIVSELIGMIPGGTALQFVFNQLWS	60
Qy	61	RLGDSGWNAFMEHVEELIDTKIEGYAKNKALSELAGIQRNLETYIQLRNEWENDIENSKA	120
Db	61	RLGDSGWNAFMEHVEELIDTKIEGYAKNKALSELAGIQRNLETYIQLRNEWENDIENSKA	120
Qy	121	QGKVANYYESLEQAVERSMPQFAVGNFEVPLLT VYVQAANLHLLLRDVS VYGKRWGWSE	180
Db	121	QGKVANYYESLEQAVERSMPQFAVENFEVPLLT VYVQAANLHLLLRDVS VYGKCGWGWSE	180
Qy	181	QKIKIYYDRQIKYTHEYTNHCNVWYNKGLERLKNKGSSYQDWYNNRFRREMTLTVL DIV	240
		:	
Db	181	QKIKIYYDKQIKYTHEYTNHCNVWYNKGLERLKNKGSSYQDWYNNRFRREMTLTVL DIV	240
Qy	241	ALFPHYDVQTYPI TTVAQLTRE VYTDPLLNFNPKLHSVSQLPSFS DMENATIRTPHLM EF	300
Db	241	ALFPHYDVQTYPI TTVAQLTRE VYTDPLLNFNPKLHSVSQLPSFS DMENATIRTPHLM EF	300
Qy	301	LRMLTIYTDWYSVGRNYYWGGH RVTSYHVGGENIRSPLYGREANQE VPRDFYFYGPVFKT	360
Db	301	LRMLTIYTDWYSVGRNYYWGGH RVTSYHVGGENIRSPLYGREANQE VPRDFYFYGPVFKT	360
Qy	361	LSKPTLRPLQQPAPAPPFNLRSL EGVEFHTSTG SFMYRERGSVDSF NELPPFPVGLPHK	420
Db	361	LSKPTLRPLQQPAPAPPFNLRSL EGVEFHTPTG SFMYRERGSVDSF NELPPFPVGLPHK	420
Qy	421	VYSHRLCHATFVRKSGTPYLT TGAI FSWTHRSABETNTIESNIITQIPLVKAYQIGSGTT	480
Db	421	VYSHRLCHATFVRKSGTPYLT TGAI FSWTHRSABETNTIESNIITQIPLVKAYQIGSGTT	480
Qy	481	VRKGPFGFTGGDILRRTGPGTF GDMRININAPLSERYRVRI RYASTTDLQFVTSINGATIN	540
		:	
Db	481	VRKGPFGFTGGDILRRTGPGTF GDMRININAPLSQRYRVRI RYASTTDLQFVTSINGTTIN	540
Qy	541	IGNFPKTINNLT LGSEGYRTVSFSTPF SFSNAQSIFRLGIQAFSGVQE VYVDKIEFIPV	600
Db	541	IGNFPKTINNLT LGSEGYRTVSFSTPF SFSNAQSIFRLGIQAFSGVQE VYVDKIEFIPV	600
Qy	601	E	601
Db	601	E	601

Carozzi et al do not teach a protein of SEQ ID NO:4.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the protein taught by Carozzi et al to make the instant SEQ ID NO:4. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Carozzi

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et al to make variants of their protein (column 11, line 40, to column 12, line 21). One of ordinary skill in the art would have been motivated to make the 6 amino acid substitutions required to convert Carozzi et al's protein to SEQ ID NO:4 because these amino acid substitutions are a conservative substitution (amino acid 514), substitutions suggested by Carozzi et al's Fig. 1 (amino acids 175, 189, 391 and 537), or are a substitution at a site that appears to tolerate any type of amino acid (amino acid 145).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the resulting modified protein to control lepidopteran pests. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Carozzi et al to do so (column 19, line 5, to column 20, line 36, particularly, column 19, lines 61-66). How or where a protein is produced or what method it is used in does not change the protein itself or further limit claims to the protein, as indicated above.

Applicant urges that the statement of the claims asserts that they are drawn to a method of using SEQ ID NO:4, but only claims 12-13 are drawn to a method.

This is not found persuasive because a method of using a protein includes the protein itself. Further this is made moot by Applicant's amendment of the claims.

Applicant urges that Carozzi et al is not a proper 102(e) type reference because they did not disclose a protein that resembled SEQ ID NO:4 prior to the priority of the instant application; their provisional 60/448810 discloses a single nucleotide sequence encoding a single protein that is not the same as SEQ ID NO:5 of the '099 patent (response pg 5).

This is not found persuasive because 60/448810 discloses a 629 amino acid long protein that comprises '099's SEQ ID NO:5; the protein in the provisional is longer by 28 amino acids at

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its amino terminus, but is otherwise identical. The alignment of Fig. 3 of 60/448810 is identical to that of '099's Fig. 1; thus the guidance of which amino acids to alter is provided in the provisional application.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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March 3, 2010

/Anne R Kubelik/

Primary Examiner, Art Unit 1638